Patient:
TOWNSEND,GEORGE

[redacted]

Client: 7736
ANIMAL MEDICAL WEST
704 ORLEANS ROAD
CHARLESTON, SC 29407

Chart:

Doctor:

Acn #:	Age/Dob:	Sex:	Collected:	Reported:
P2533250	8,	M,C	10/15/97	10/17/97 2:18PM

Comment: STOMACH PANCREAS KIDNEY

TESTS	RESULTS	REFERENCE VALUES

BIOPSY(5 SECTIONS)

Microscopic Description:

Received for evaluation are multiple fixed tissues representing a partial necropsy of an adult male Labrador Retriever.

Microscopically, sections of stomach are found to contain several areas of recent ulceration and hemorrhage. Adjacent mucosa is affected by mild to moderate inflammation representing infiltrates of lymphocytes and plasma cells. Numerous prominent lymphoid mucosal nodules are recognized. Some segments contain colonizing bacteria within surface crypts and mucus. The ulcerated sites are colonized by mixed bacteria. A section of small intestine has mucosal inflammation representing infiltrates of lymphocytes and plasma cells. The lumen of one section of small intestine is filled with blood. Sections of liver are affected by random and portal inflammation representing infiltrates of lymphocytes, plasma cells, and macrophages. Most lobules contain abundant cytoplasmic and extracellular bile pigment. Mild bile duct hyperplasia is seen in some fields. A few lobules are affected by early fibrosis. Hepatocytes are generally swollen and a few random necrotic hepatocytes are identified. Small venules are often dilated. A section of kidney contains limited interstitial inflammation representing plasma cells and lymphocytes. Limited early fibrosis is seen in some fields. Bile casts are noted in a few tubules.

Pathological Diagnosis:

1. SEVERE ACUTE TO SUBACUTE ULCERATIVE HEMORRHAGIC GASTRITIS.
2. MODERATE CHRONIC HEPATITIS WITH SEVERE CHOLESTASIS AND MINIMAL NECROSIS.
3. MODERATE CHRONIC LYMPHOPLASMACYTIC GASTRITIS.
4. MILD CHRONIC INTERSTITIAL NEPHRITIS, KIDNEY.
5. MILD TO MODERATE LYMPHOPLASMACYTIC ENTERITIS, SMALL INTESTINE.

Comment:

This dog has extensive evidence of chronic liver and gastrointestinal disease. The liver changes are non-specific, however, the presence of scattered necrotic hepatocytes suggests the possibility of a toxic pathogenesis.

Sections of pancreas and spleen contain no significant changes.

REPORT CONTINUED ON NEXT FORM

Patient:
TOWNSEND,GEORGE 383

[redacted]

Client: 7736
ANIMAL MEDICAL WEST
784 ORLEANS ROAD
CHARLESTON, SC 29407

Chart: 383

Doctor: GARRO

Acn #:	Age/Dob:	Sex:	Collected:	Reported:
X1187951	8.	M,C	10/14/97	10/15/97 2:42PM

TESTS	RESULTS		REFERENCE VALUES
T4	1.2	MCG/DL	1.0-4.0
URINE PROFILE			
URINALYSIS			
PH	7.0		5.5-7.5
SPECIFIC GRAVITY	1.024		1.010-1.050
APPEARANCE	CLEAR		CLEAR
COLOR	DARK YELLOW		
TRIPLE PHOS. CRYSTALS	NONE		
AMORPHOUS PHOSPHATES	NONE		
CALCIUM OXALATE CRYSTALS	NONE		
URIC ACID CRYSTALS	NONE		
PROTEIN	[redacted]		NEG
GLUCOSE	[redacted]		NEG
KETONE	NEG		NEG
BILIRUBIN	[redacted]		NEG
BLOOD	NEG		NEG
UROBILINOGEN	NORMAL		NORMAL
WBC	NONE	HPF	0-5
RBC	NONE	HPF	0-10
EPITHELIA	MODERATE		0-2
BACTERIA	[redacted]		NONE
TOTAL PROTEIN,URINE	[redacted]	MG/DL	10-50
CREATININE,URINE	102.0	MG/DL	100-500
UREA,URINE	[redacted]	MG/DL	1000-2500
GLUCOSE,URINE	[redacted]	MG/DL	10-55
CALCIUM,URINE	5.5	MG/DL	2-10
PHOSPHORUS,URINE	68.8	MG/DL	50-200
SODIUM,URINE	122.8	MEQ/L	20-170
POTASSIUM,URINE	37.7	MEQ/L	20-120
PROTEIN/CREATININE RATIO			
CREATININE,URINE	102.0	MG/DL	100-500
TOTAL PROTEIN,URINE	[redacted]	MG/DL	10-50
PROTEIN/CREATININE RATIO	1.1	RATIO	<1.5

**** FINAL REPORT **** 10/15/97 2:42PM

MENT OF HEALTH AND HUMAN SERVICES
HEALTH SERVICE
ND DRUG ADMINISTRATION (HFV-210)
IERS LANE
LE, MD. 20857

ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT

(Forward to the address at left. Attach all correspondence that pertains to this reaction)

PQC # 6674

Form Approved: OMB No. 0910-0012
Expiration Date: May 31, 1987

92409

This report is required by law (21 CFR 510.300). Failure to report can result in withdrawal of approval of the application.

RT SOURCE AND ADDRESS (Mfr., Distr.)

PFIZER INC
812 Springdale Drive
Exton, PA 19341

2. DATE SENT TO FDA *(Month, day, year)*

MAY 4 1998

3. TYPE OF REPORT
☒ INITIAL
☐ FOLLOW UP TO REPORT

E. ADDRESS AND PHONE NO. OF ATTENDING VETERINARIAN (In c)

Dr. Lisa Gavro
704 Orleans Rd
Charleston, SC 29407 803-766-7387

5. NAME OR CASE IDENTIFICATION OF OWNER (In confidence)

Jean Townsend

SECTION I - DRUG DATA

DE NAME AND GENERIC NAME(S) OF ACTIVE INGREDIENTS(S) (Include form and strength - ex., tab 500mg.)

carprofen 75mg/caplet
4/caplets

7a. NAME OF MANUFACTURER

Pfizer Inc

b. NADA NO.

141-053

NUMBER

own

9. DOSAGE REGIMEN AND ROUTE (Ex. 250 mg., q 12h p.o.)

75mg bid PO

10. DATE(S) OF ADMINISTRATION

9-9-97 TO 10-8-97

NESS/REASON FOR USE OF THIS DRUG

to treat osteoarthritis

12. DRUG WAS ADMINISTRATED BY
☐ VETERINARIAN, STAFF
☐ OWNER, OTHER

SECTION II - ANIMAL DATA

NUMBER OF ANIMALS IN THIS INCIDENT

ATED WITH DRUG	b. REACTED	c. DIED
1	1	1 euthanized

14. REACTING ANIMALS(S)

a. SPECIES: Canine
b. BREED: Labrador Retriever
c. AGE: 12.4Y
d. WEIGHT: 63#
e. SEX: ☐ FEMALE ☒ MALE ☐ PREGNANT ☒ NEUTERED

NCOMITANT MEDICAL PROBLEMS

none

ERALL STATE OF HEALTH AT TIME OF CTION

OD ☒ FAIR ☐ POOR ☐ CRITICAL

17. DID ANY NEW ILLNESS DEVELOP OR DID INITIAL DIAGNOSIS CHANGE AFTER SUSPECT DRUG STARTED

☐ NO ☒ YES (Explain) day developed vom, anorexia, elevated liver and kidney enzymes

CONCOMITANT DRUGS ADMINISTERED

NAME OF DRUG	ROUTE	DOSAGE REGIMEN	DATE(S) OF ADMINISTRATION
NONE			

FOR FDA USE ONLY

	D	NAI
	PR	AI
	PO	AP
	R	AL
	NC	
	CR	CONT

COMMENT

SECTION III - REACTION DATA

PQC #

19. DESCRIBE SUSPECTED ADVERSE REACTION: INCLUDE ALL SIGNS, RESULTS OF PERTINENT LAB TESTS, NECROPSY RESULTS, POSSIBLE CONTRIBUTING FACTORS ETC. ALSO, INCLUDE IN THIS SECTION PRODUCT INEFFECTIVENESS AND PRODUCT DEFECTS SUCH AS CRACKED TABLETS, CLOUDY SOLUTION, ETC.

Dog was stated on Rimadyl on 9-9-97. Owner reported anorexia on 10-9-97. Dog started vomiting on 10-8-97. Dog was started on I.V. fluids and carnitine on 10-8-97. Chemistry panel from 10-10-97 revealed ↓albumin (2.6), ↑ lipase (1755), ↑BUN (112), ↑ creatinine (565), ↑phosphorus (10.87), ↑bilirubin (17.85). Chemistry panel was repeated on 10-13-97. It showed ↓albumin (1), ↓globulin 2.3, ↓total protein (3.3), ↑ALT (244), ↑BUN (59), ↑creatinine (2.91), ↑bilirubin (8.37). Dog developed petechiae, bloody diarrhea and was euthanized. Histopathology pending. Dr. Gaunt feels Rimadyl caused liver and renal failure in this dog.

20. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED REACTION

☒ HIGH ☐ MEDIUM ☐ LOW ☐ NO ATTENDING VET.

21. LENGTH OF TIME BETWEEN LAST ADMINISTRATION OF SUSPECT DRUG AND ONSET OF REACTION.	22. DATE OF ONSET (Mo., day, yr.)	23. DURATION OF REACTION (Hrs., days, etc.)
	10-7-97	6 day 3

24. WAS THE ADVERSE REACTION TREATED?

☐ NO ☒ YES (Describe treatment)

I.V. fluids, carnitine

25. OUTCOME OF REACTION TO DATE

☒ DIED (Give Date) 10-13-97
☐ REMAINS UNDER TREATMENT
☐ ALIVE WITH SEQUELAE
☐ RECOVERED
☐ UNKNOWN

26. WHEN REACTION APPEARED, TREATMENT WITH SUSPECT DRUG:

☐ HAD ALREADY BEEN COMPLETED
☐ DISCONTINUED DUE TO THE REACTION
☐ DISCONTINUED, REPLACED WITH ANOTHER DRUG
☐ DISCONTINUED, REINTRODUCED LATER
☐ CONTINUED AT ALTERED DOSE
☒ OTHER (Explain) continued as prescribed

AND THE REACTION

☒ CONTINUED
☐ STOPPED
☐ RECURRED
☐ OTHER (Explain)

SECTION IV - HISTORY

27. HAD ANIMAL(S) BEEN PREVIOUSLY EXPOSED TO THIS DRUG? ☒ NO ☐ YES ☐ UNKNOWN

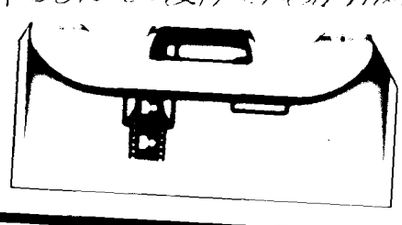
28. DID ANIMAL(S) PREVIOUSLY REACT TO THIS DRUG? ☒ NO ☐ YES ☐ UNKNOWN

29. HAD ANIMAL(S) PREVIOUSLY REACTEDTO OTHER DRUGS? ☒ NO ☐ YES (If yes, give drug(s) and reaction if known) ☐ UNKNO

30. HAS THE ATTENDING VETERINARIAN SEEN SIMILAR REACTIONS TO THIS DRUG IN ANY OTHER ANIMALS?

☒ NO ☐ YES (If yes, summarize)

31. NAME AND TITLE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED INFORMATION (Type or print)	32. SIGNATURE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED INFORMATION
Michael D. Owsley Manager Technical Services/Veterinarian	



ARTMENT OF HEALTH AND HUMAN SERVICES
C HEALTH SERVICE
D AND DRUG ADMINISTRATION (HFV-210)
FISHERS LANE
CVILLE, MD. 20857

ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT

(Forward to the address at left. Attach all correspondence that pertains to this reaction)

PQC # 66674B

Form Approved: OMB No. 0910-0012
Expiration Date: May 31, 1987

92409

This report is required by law (21 CFR 510.300). Failure to report can result in withdrawal of approval of the application.

1. REPORT SOURCE AND ADDRESS (Mfr., Distr.)

PFIZER INC
812 Springdale Drive
Exton, PA 19341

2. DATE SENT TO FDA *(Month, day, year)*

MAY 4 1998

3. TYPE OF REPORT
☐ INITIAL
☒ FOLLOW UP TO REPORT
MAY 4 1998

4. NAME, ADDRESS AND PHONE NO. OF ATTENDING VETERINARIAN (In confidence)

Dr. Lisa Garro
704 Orleans Rd.
Charleston, SC 29407 803-766-7387

5. NAME OR CASE IDENTIFICATION OF OWNER (In confidence)

Jean Townsend

SECTION I - DRUG DATA

6. TRADE NAME AND GENERIC NAME(S) OF ACTIVE INGREDIENTS(S) (Include dose form and strength - ex., tab 500mg.)

rdy/caplets caprofen 75mg/caplet

7a. NAME OF MANUFACTURER

Pfizer Inc

b. NADA NO.

141-053

8. NUMBER

known

9. DOSAGE REGIMEN AND ROUTE (Ex. 250 mg., q 12h p.o.)

75mg bid po

10. DATE(S) OF ADMINISTRATION

9-9-97 To 10-8-97

11. ILLNESS/REASON FOR USE OF THIS DRUG

front osteoarthritis

12. DRUG WAS ADMINISTRATED BY
☐ VETERINARIAN, STAFF
☒ OWNER, OTHER

SECTION II - ANIMAL DATA

13. NUMBER OF ANIMALS IN THIS INCIDENT

TED WITH DRUG	b. REACTED	c. DIED

14. REACTING ANIMALS(S)

a. SPECIES	b. BREED

c. AGE	d. WEIGHT

e. SEX ☐ FEMALE ☐ MALE ☐ PREGNANT ☐ NEUTERED

15. COMITANT MEDICAL PROBLEMS

16. RALL STATE OF HEALTH AT TIME OF TION
☐ FAIR ☐ POOR ☐ CRITICAL

17. DID ANY NEW ILLNESS DEVELOP OR DID INITIAL DIAGNOSIS CHANGE AFTER SUSPECT DRUG STARTED
☐ NO ☐ YES (Explain)

CONCOMITANT DRUGS ADMINISTERED

NAME OF DRUG	ROUTE	DOSAGE REGIMEN	DATE(S) OF ADMINISTRATION

FOR FDA USE ONLY

___ D NAI
___ PR AI
___ PO AP
___ R AL
___ NC
___
___

CR CONT

COMMENT

1932

SECTION III - REACTION DATA

PQC #

19. DESCRIBE SUSPECTED ADVERSE REACTION: INCLUDE ALL SIGNS, RESULTS OF PERTINENT LAB TESTS, NECROPSY RESULTS, POSSIBLE CONTRIBUTING FACTORS ETC. ALSO, INCLUDE IN THIS SECTION PRODUCT INEFFECTIVENESS AND PRODUCT DEFECTS SUCH AS CRACKED TABLETS, CLOUDY SOLUTION, ETC.

Pathology report is the following:

1. severe acute to subacute ulcerative hemorrhagic gastritis
2. moderate chronic active hepatitis with severe cholestasis and minimal necrosis
3. moderate chronic lymphoplasmacytic gastritis
4. mild chronic interstitial nephritis, kidney
5. mild to moderate lymphoplasmacytic enteritis, small intes

The report commented that dog has extensive evidence of chronic liver and gastrointestinal disease. The liver changes are non-specific. However, the presence of scattered necrotic hepatocytes suggests the possibility of toxic pathogenesis

20. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED REACTION

☐ HIGH ☐ MEDIUM ☐ LOW ☐ NO ATTENDING VET.

21. LENGTH OF TIME BETWEEN LAST ADMINISTRATION OF SUSPECT DRUG AND ONSET OF REACTION.	22. DATE OF ONSET (Mo.,day,yr.)	23. DURATION OF REACTION (Hrs., days,

24. WAS THE ADVERSE REACTION TREATED?
☐ NO ☐ YES (Describe treatment)

25. OUTCOME OF REACTION TO DATE
☐ DIED (Give Date)
☐ REMAINS UNDER TREATMENT
☐ ALIVE WITH SEQUELAE
☐ RECOVERED
☐ UNKNOWN

26. WHEN REACTION APPEARED, TREATMENT WITH SUSPECT DRUG:
☐ HAD ALREADY BEEN COMPLETED
☐ DISCONTINUED DUE TO THE REACTION
☐ DISCONTINUED, REPLACED WITH ANOTHER DRUG
☐ DISCONTINUED, REINTRODUCED LATER
☐ CONTINUED AT ALTERED DOSE
☐ OTHER (Explain)

AND THE REACTION

☐ CONTINUED
☐ STOPPED
☐ RECURRED
☐ OTHER (Explain)

SECTION IV - HISTORY

7. HAD ANIMAL(S) BEEN PREVIOUSLY EXPOSED TO THIS DRUG? ☐ NO ☐ YES ☐ UNKNOWN

8. DID ANIMAL(S) PREVIOUSLY REACT TO THIS DRUG? ☐ NO ☐ YES ☐ UNKNOWN

9. HAD ANIMAL(S) PREVIOUSLY REACTEDTO OTHER DRUGS? ☐ NO ☐ YES (If yes, give drug(s) and reaction if known) ☐ UNKNOWN

HAS THE ATTENDING VETERINARIAN SEEN SIMILAR REACTIONS TO THIS DRUG IN ANY OTHER ANIMALS
☐ NO ☐ YES (If yes, summarize)

NAME AND TITLE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF PORTED INFORMATION (Type or print)	32. SIGNATURE OF INDIVIDUAL RESPONSIBLE FOR ACCURACY OF REPORTED INFORMATION
Michael J. VanSchoyck Managing Technical Services Veterinarian	

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 2 2004

Jean Townsend
1769 Clark Hills Circle
Johns Island, SC 29455

In reply refer to:
File No. F04-12011

Dear Ms. Townsend:

This is in response to your Freedom of Information Act (FOIA) request received by the Food and Drug Administration (FDA) on August 6, 2004, in which you requested a copy of the ADE report containing the causality scoring for your dog George.

Enclosed is a copy of a printout from the FDA/CVM Adverse Drug Event (ADE) database pertaining to your dog. The printout contains the FDA's causality assessment of the clinical signs described in your animal's Adverse Drug Experience (ADE) report.

Individual animal ADE reports represent only part of the information on drug safety of a product in the post-approval period. The FDA uses these reports to estimate the frequency and severity of reported signs. The individual report is not intended to serve as a veterinary medical opinion about single episodes but to help understand the entire drug safety and efficacy profile of the product. This profile is used to support or revise critical label information about the product.

With that understanding, the score that you see beside each clinical sign on this report represents the expert opinion of a reviewer, all of whom are practicing clinical veterinarians, based on the information available on your animal. The score represents an assessment made with consideration for previous experience with the drug, alternative causal agents or conditions that your animal may have received or had, the timing of the reaction, the dose of the drug and, if relevant, whether the sign abated or worsened upon withdrawal or re-introduction of the drug.

Causality scores correspond to the following opinion regarding a drug/reaction:

-9	The drug was not used for a labeled indication
-7 to -8	Information was lacking and/or no conclusion could be made
-1 to -6	The symptom or sign is remotely likely to be drug-related
0-2	The symptom or drug is possibly related to the drug
3-5	The symptom or drug is probably related to the drug
6-7	The symptom or drug is definitely related to the drug

As you will note, the enclosed records contain certain business or personal information that is not disclosable to the general public. Copies of these records will be disseminated to other requesters only after thorough review and deletion of those portions not disclosable to the general public.

The following charges will be included in a monthly invoice:

Reproduction	3 pages	$ .30
Search	1 hour	$ 36.00
Total		$ 36.30

The above charges may not reflect final charges for this request. Please **DO NOT** send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

Sincerely,

Alfan B. Dangin
Paralegal Specialist
Communications Staff
Center for Veterinary Medicine

Enclosure

ADE Reports Search Criteria

Prepared on 10/29/2004

DER PACKAGE DESCRIPTIONS

				From	To
Document : N 141053	**Sub Num** 57	**Drug :**	**Corr Date:**		

ADE REVIEWS

Report Source:		**Source Report ID:**	
Country:		**NDC:**	-
State:		**Product Lot #:**	
ZIP:		**Report Quality:**	

ADE EPISODES

				From	To	Unit
Dosage:	**Species:**	DOG	**Age:**			
Administered By:	**Breed:**	RETRIEVER, LABRA	**Weight:**			
Extra Label:	**Gender:**	MALE, NEUTERED	**Episode Date:**			
Vet Opinion:	**Health Status:**		**Reason for Use:**			
	Route:					

ADE CONCOMITANTS

Status:	**Description:**

ADE ASSESSMENTS

	Onset Value		Onset	Causality Assessment	
Clinical Detail	**From**	**To**	**Denom**	**From**	**To**
G DEATH(EUTHANIZED)				0	6

Number of Reviews Retrieved: 1

FDA/CVM - ADE Reports - CVM Response

Prepared on 10/29/2004

Drug Name: CARPROFEN

Document ID: N 141053 **Submission ID:** L 57 **Package ID:** A 1 **Corrsp Date:** 05/04/1998

Source: Report from sponsor or distibutor of drug **Source Report Id:**

Country: United States **NDC:**

State: UNKNOWN **Zip:** XXXXX **Product Lot No:**

Report Quality: Unknown

Episode Date: 05/04/1998

Dosage: Recommended dose

Route: Oral (all other)

Dose Description:

Extra Label: None

Reason For Use:

Health Status: Unknown

Administered By: Unknown

Vet Opinion: Unknown

Concomitants: No

 # Treated: 1

 # Reacted: 1

 # Died: 1

Species: DOG

Breed: Retriever, labrador

Age: 12 YR

Weight: 63 LB

Gender: Male, neutered

Evaluation Comments:

"RTX:IV FLUIDS, CARAFATE;BUN=112,CREAT= 5.65,BIL=17.8 10/10;BUN=54,CREAT=2.9,BIL =8.2,ALB=1,TP=3.3 10/13;*F/U 57AB:PR- ULCER,HEMORRH GASTRITIS;CHRONIC ACTIVE HEPATITIS W/SEVERE CHOLESTASIS;CHRONIC INTERSTITIAL NEPHRITIS-POSSIB. TOXIC"

Causality Assessment	Time To Onset		Clinical Detail:
3	3 WK	D	DIARRHEA, BLOODY
3	5 WK	D	PR-GI, LESION(S)
3	17 DA	D	VOMITING
3	5 WK	G	ALBUMIN LO, BLD
1	4 WK	G	AMYLASE HI, BLD
3	16 DA	G	ANOREXIA
3	4 WK	G	BILIRUBIN(TOT) HI, BLD
3	4 WK	G	BUN HI, BLD
3	15 DA	G	COLLAPSE
3	4 WK	G	CREATININE HI, BLD
3	5 WK	G	DEATH(EUTHANIZED)

3	5 WK	G	GLOBULIN LO, BLD
3	3 WK	G	ICTERUS, BODY
3	4 WK	G	P HI, BLD
3	4 WK	G	PROTEIN(TOT) LO, BLD
3	3 WK	G	WEIGHT LOSS
3	5 WK	L	PR-LIVER, LESION(S)
3	5 WK	U	PR-KIDNEY(S), LESION(S